Cannock Chase Clinical Commissioning Group
South East Staffordshire and Seisdon Peninsula Clinical Commissioning Group
Stafford and Surrounds Clinical Commissioning Group
East Staffordshire Clinical Commissioning group

South Staffordshire Area Prescribing Group (APG) Update

A resource for South Staffordshire Clinical Commissioning Group Members

August 2017 Meeting

Welcome from the chair...

Dear all,

The local area prescribing group is striving to move forward to keep the local medicine formulary up to date with the latest medication developments and safety advise. The latest newsletter contains the most current safety update from the MHRA. We have developed a summary table to help with the prescribing of DOACS. It is important to prescribe within the product licence.

The increasing use of opiates for chronic pain is becoming an increasing complex issue. I would therefore urge you to review the opioid prescribing updates. The APG is also still working to improve shared care prescribing. If the shared care prescribing principles are not being followed could please advise the medicines team.

***Dr. Mark Stone* - Chair, South Staffordshire Area Prescribing Group**

In this newsletter:

Shared care arrangement reviews….

Work is continuing, in collaboration with local Trusts, to produce and implement a set of Principles of Shared Care to help develop Essential Shared Care Agreements (ESCA's) locally and to support the safe prescribing of shared care drugs.

Currently the CCG medicines optimisation teams are working with Royal Wolverhampton NHS Trust, Burton Hospital NHS Foundation Trust and South Staffordshire & Shropshire Healthcare NHS Trust to update ESCA's in-line with these principles. Further information will be provided as the work continues.

Once approved these will uploaded onto the net.Formulary site for reference.

NICE technology appraisal update

TA461: Roflumilast for treating chronic obstructive pulmonary disease (26 July 2017)

Roflumilast, as an add-on to bronchodilator therapy, is recommended as an option for treating severe chronic obstructive pulmonary disease in adults with chronic bronchitis, only if:

- the disease is severe, defined as a forced expiratory volume in 1 second (FEV1) after a bronchodilator of less than 50% of predicted normal, and
- the person has had 2 or more exacerbations in the previous 12 months despite triple inhaled therapy with a long-acting muscarinic antagonist, a long-acting beta-2 agonist and an inhaled corticosteroid.

Treatment with roflumilast should be started by a specialist in respiratory medicine.

Roflumilast has been added to the formulary as a RED drug.
Roflumilast is recommended as a treatment option within the updated local COPD guidelines however at present prescribing should remain within secondary care until a formulary application is received to review the appropriateness of the transfer of prescribing to primary care.

TA464: Bisphosphonates for treating osteoporosis (9 August 2017)

1.1 Oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) are recommended as options for treating osteoporosis in adults only if:

- the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis (recommendations 1.1 and 1.2) and
- the 10 year probability of osteoporotic fragility fracture is at least 1%.

1.2 Intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended as options for treating osteoporosis in adults only if:

- the person is eligible for risk assessment as defined in NICE's guideline on osteoporosis (recommendations 1.1 and 1.2) and
- the 10 year probability of osteoporotic fragility fracture is at least 10% or
- the 10 year probability of osteoporotic fragility fracture is at least 1% and the person has difficulty taking oral bisphosphonates (alendronic acid, ibandronic acid or risedronate sodium) or these drugs are contraindicated or not tolerated.

1.3 Estimate the 10 year probability of osteoporotic fragility fracture using the FRAX or QFracture risk tools, in line with NICE's guideline on osteoporosis.

1.4 The choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient, or their carers, about the advantages and disadvantages of the treatments available. If generic products are available, start treatment with the least expensive formulation, taking into account administration costs, the dose needed and the cost per dose.

1.5 These recommendations are not intended to affect treatment with alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid that was started in the NHS before this guidance was published. Adults having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

This guidance aligns previous NICE TA guidance on the use of bisphosphonates for preventing osteoporotic fragility fractures with NICE's guideline on *Osteoporosis: assessing the risk of fragility fracture.* Previous NICE technology appraisal guidance TA160 and TA161 did not:

- **include recommendations for men**
- **cover bisphosphonate treatments available, such as ibandronic acid and zoledronic acid.**

MHRA Drug Safety Updates

Denosumab (Prolia, Xgeva▼): reports of osteonecrosis of the external auditory canal

Denosumab is associated with a risk of osteonecrosis of the jaw. Osteonecrosis of the external auditory canal has also been reported with denosumab.

Advice for healthcare professionals:

- the possibility of osteonecrosis of the external auditory canal should be considered in patients receiving denosumab who present with ear symptoms including chronic ear infections or in those with suspected cholesteatoma
- possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma
- advise patients to report any ear pain, discharge from the ear, or an ear infection during denosumab treatment
- report cases of osteonecrosis of any bone suspected to be associated with denosumab or any other medicine on a Yellow Card

Brimonidine gel (Mirvaso): risk of systemic cardiovascular effects; not to be applied to damaged skin

Systemic cardiovascular effects including bradycardia, hypotension, and dizziness have been reported after application. It is important to avoid application to irritated or damaged skin, including after laser therapy.

Advice for healthcare professionals:

- cases of bradycardia, hypotension (including orthostatic hypotension), and dizziness after application of brimonidine gel have been reported, some of which required hospitalisation
- some cases were associated with application of brimonidine gel after laser procedures to the skin, which possibly caused increased absorption of the gel
- warn patients not to apply brimonidine gel to irritated or damaged skin, including after laser therapy to the skin.

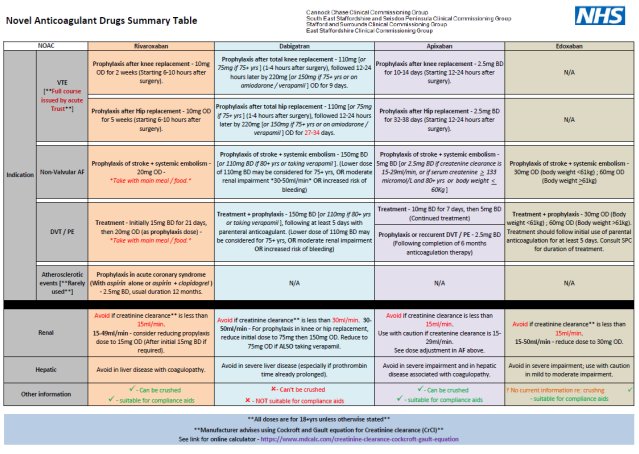
Direct Oral Anticoagulant Drug (DOAC) summary table

A summary document has been developed with the licensed doses and monitoring requirements of all the DOACs. There have been a number of requests from secondary care for GPs to prescribe DOACs out-side of the product licenses which has raised safety concerns. If prescribers have any concerns over requests for DOAC prescribing they should contact a member of the CCG medicines optimisation team and report this through a DATIX.

Use of the DOACs in patients with reduced renal function should be based on creatinine clearance rather than eGFR. Within EMIS there is the function to calculate creatinine clearance by running a template:

1. Open up a consultation entry
2. Select 'Run template' from the menu ribbon at the top of the page
3. Search 'Estimated creatinine clearance (Cockroft Gault)' and select the template
4. Fill in the required parameters and save the template then the consultation entry

That should then enter the read code for creatinine clearance and also record the value in the patients consultation notes and on the investigations tab.



Novel Anticoagulant Drugs Summary Table

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NHS

NOAC		Rivaroxaban	Dabigatran	Apixaban	Edoxaban
Indication	VTE [**Full course issued by acute Trust**]	Prophylaxis after knee replacement - 10mg OD for 2 weeks (Starting 6-10 hours after surgery).	Prophylaxis after total knee replacement - 110mg [or 75mg if 75+ yrs] (1-4 hours after surgery), followed 12-24 hours later by 220mg [or 150mg if 75+ yrs or on amiodarone / verapamil] OD for 9 days.	Prophylaxis after knee replacement - 2.5mg BD for 10-14 days (Starting 12-24 hours after surgery).	N/A
		Prohylaxis after Hip replacement - 10mg OD for 5 weeks (starting 6-10 hours after surgery).	Prophylaxis after total hip replacement - 110mg [or 75mg if 75+ yrs] (1-4 hours after surgery), followed 12-24 hours later by 220mg [or 150mg if 75+ yrs or on amiodarone / verapamil] OD for 27-34 days.	Prophylaxis after Hip replacement - 2.5mg BD for 32-38 days (Starting 12-24 hours after surgery).	N/A
	Non-Valvular AF	Prophylaxis of stroke + systemic embolism - 20mg OD - *Take with main meal / food.*	Prophylaxis of stroke + systemic embolism - 150mg BD (or 110mg BD if 80+ yrs or taking verapamil). (Lower dose of 110mg BD may be considered for 75+ yrs, OR moderate renal impairment *30-50ml/min* OR increased risk of bleeding)	Prophylaxis of stroke + systemic embolism - 5mg BD (or 2.5mg BD if creatinine clearance is 15-29ml/min, or if serum createnine ≥ 133 micromol/L and 80+ yrs or body weight ≤ 60kg)	Prophylaxis of stroke + systemic embolism - 30mg OD (Body weight >61kg) , 60mg OD (Body weight ≤61kg)
	DVT / PE	Treatment - Initially 15mg BD for 21 days, then 20mg OD (as prophylaxis dose) - *Take with main meal / food.*	Treatment + prophylaxis - 150mg BD (or 110mg if 80+ yrs or taking verapamil), following at least 5 days with parenteral anticoagulant. (Lower dose of 110mg BD may be considered for 75+ yrs, OR moderate renal impairment OR increased risk of bleeding)	Treatment - 10mg BD for 7 days, then 5mg BD (Continued treatment) Prophylaxis or reccurent DVT / PE - 2.5mg BD (Following completion of 6 months anticoagulation therapy)	Treatment + prophylaxis - 30mg OD (Body weight <61kg) , 60mg OD (Body weight >61kg). Treatment should follow initial use of parenteral anticoagulation for at least 5 days. Consult SPC for duration of treatment.
	Atherosclerotic events [**Rarely used**]	Prophylaxis in acute coronary syndrome (With aspirin alone or aspirin + clopidogrel) - 2.5mg BD, usual duration 12 months.	N/A	N/A	N/A
Renal		Avoid if creatinine clearance** is less than 15ml/min. 15-49ml/min - consider reducing propylaxis dose to 15mg OD (After initial 15mg BD if required).	Avoid if creatinine clearance** is less than 30ml/min. 30-50ml/min - For prophylaxis in knee or hip replacement, reduce initial dose to 75mg then 150mg OD. Reduce to 75mg OD if ALSO taking verapamil.	Avoid if creatinine clearance is less than 15ml/min Use with caution if createnine clearance is 15-29ml/min. See dose adjustment in AF above.	Avoid if creatinine clearance** is less than 15ml/min. 15-50ml/min - reduce dose to 30mg OD.
Hepatic		Avoid in liver disease with coagulopathy.	Avoid in severe liver disease (especially if prothrombin time already prolonged).	Avoid in severe impairment and in hepatic disease associated with coagulopathy.	Avoid in severe impairment, use with caution in mild to moderate impairment.
Other information		✓ - Can be crushed ✓ - suitable for compliance aids	✖ - Can't be crushed ✖ - NOT suitable for compliance aids	✓ - Can be crushed ✓ - suitable for compliance aids	? No current information re: crushing ✓ - suitable for compliance aids

All doses are for 18+yrs unless otherwise stated
Manufacturer advises using Cockroft and Gault equation for Creatinine clearance (CrCl)
See link for online calculator - https://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation

The summary will be available on the net.formulary site at http://www.southstaffordshirejointformulary.nhs.uk/docs/apg/Cardiovascular-System/

South Staffordshire Area Prescribing Group (APG) Update - August 2017

Formulary applications approved

Insulin degludec

Insulin degludec has been approved for inclusion within the South Staffordshire formulary as an alternative choice of long-acting insulin analogue for patients not controlled (or having unacceptable hypoglycaemia) on determir or glargine insulins in type 1 and type 2 diabetics.

Insulin degludec is available in 2 strengths (100units/mL and 200units/mL) therefore caution is advised when prescribing and dispensing to ensure the correct preparation is chosen.

Similar to high strength insulin glargine, the high strength insulin degludec (200units/mL) it was agreed to be added to the formulary as an AMBER 1 drug which requires specialist initiation and a RICaD will be developed to support the drugs introduction (this will be reviewed in 6 months' time). Until the RICaD is produced and approved it will be added to the formulary as RED (specialist prescribing only). The lower strength insulin degludec (100units/mL) will be added as GREEN.

Gluco-Juce

Due to the changes in sugar content of Lucozade Energy Original, which is recommended in the BNF to treat hypoglycaemia, Burton Hospitals have requested Gluco-Juce to be available for prescribing to type 1 diabetic paediatric patients. Similar sugar content changes are expected for other branded drinks in the near future. Gluco-Juce is a glucose solution (15g in 60mL) which is available in a ready to use pack.

Gluco-Juce has therefore been approved for inclusion within the South Staffordshire formulary as GREEN for prescribing to type 1 diabetic paediatric patients ONLY. All other patients should be advised to purchase this, or similar products, for the management of hypoglycaemia.

Low molecular weight heparins

There are ongoing supply problems with low molecular weight heparins. In addition to the supply issues, a bio-similar enoxaparin product will be launched in September 2017. The MHRA has stated that unintentional switching should not occur between the 2 products (Inhixa® (bio-similar enoxaparin) and Clexane®) therefore enoxaparin should be prescribed by brand to avoid confusion.

Contact details

If you have any questions relating to the net.Formulary or the Area Prescribing Group please send these to southstaffs.medsoptimisation@nhs.net or use the feedback tab through the net.Formulary site.

Next APG date:

Friday 13th October 2017

Any papers or agenda items need to be submitted by 7th October 2017.

South Staffordshire Formulary updates

As part of the ongoing review of the local formulary the following significant changes have been approved:

- Diclofenac has been changed from GREEN to AMBER 1 for new initiations. Following updated safety concerns with diclofenac it should not be used as a first-line NSAID hence the reclassification.
- Colifoam® (hydrocortisone) enemas have been added to the formulary as they are considerable more cost-effective than Predfoam® (prednisolone) enemas (£9.33 compared to £187.00 (for 14 doses)). Gastroenterologists at Burton Hospital have supported the use of Colifoam® as there is no clinical difference between the products or the situations where they would be used. Confirmation is still being sought from UHNM and RWT teams.
- Sildenafil will have a note added to state usual monthly quantity should be 4-8 tablets. NHS prescriptions above 8 tablets per month should be based on individual clinical circumstances and be advised by a specialist in erectile dysfunction.
- Asasantin MR® (dipyridamole + aspirin) has been discontinued. To be removed from formulary with an additional note to state: *existing patients should be reviewed to change to clopidogrel as per NICE guidance.*
- Fluoxetine 20mg dispersible tablets now available and included within the formulary for patients with swallowing difficulties as more cost-effective than other solutions (*Costs per 28 days:* 20mg dispersible tablets (SF) £3.44, 20mg/5ml oral solution £5.68 and 20mg/5ml oral solution sugar free £25.90)
- Omeprazole MUPS tablets are licensed in patients >1year old and doses smaller than 10mg can be achieved by dispersing tablets in water and drawing up the correct dose. This method of administration is preferable than the prescribing of unlicensed omeprazole liquids for patients >1years of age.
- Morphine MR preparations – where appropriate prescribing is preferred as Zomorph® capsules. Zomorph® are the most cost-effective preparation and are able to be opened and sprinkled over/mixed with food if there are swallowing difficulties.
- Nutilis-clear® has been added as the first-line choice for feed thickener on the formulary. This is in-line with SSOTP dietetic and speech and language therapist's recommendations.
- Edoxaban has been added to the DOAC section as green in-line with the other NICE recommended DOACs.
- Weekly GLP1 mimetics exenatide (Bydureon®) and dulaglutide (Trulicity®) have been reclassified to amber1 they will be started by a diabetes specialist in line with NICE guidance for diabetes and then transferred over to primary care. This is in-line with the other GLP1 products already within the formulary.

Work is ongoing to review the current formulary to ensure it is up-to-date.

If you identify any issues with the website please raise these via southstaffs.medsoptimisation@nhs.net so that it can be followed up.

Asthma and COPD guidelines

These are now available on the South Staffordshire formulary website - net.Formulary.

http://www.southstaffordshirejointformulary.nhs.uk/docs/apg/Respiratory-System/